K121264

5. 510(k) Summary

AUG 27 2012

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Address of Manufacturer:

Medtronic Powered Surgical Solutions
4620 North Beach Street
Fort Worth, TX 76137
(817) 788-6400 Phone
(817) 788-6222 Facsimile

Establishment Registration Number: 1625507

Contact Person:

Jeffrey Henderson
VP, Quality, Clinical & RA

Date: August 10, 2012

Trade or Proprietary Name:

TRITON Electric High Torque Handpiece and Software Module

IPC System with the TRITON High Torque Handpiece

Common usual or Classification Name:

21 CFR 882.4360, Product Code HBC, Class II – Electric cranial drill motor

21 CFR 882.4310, Product Code HBE, Class II - Powered simple cranial drills, burrs, trephines, and their accessories

21 CFR 888.1100, Product Code HRX, Class II - Arthroscope

21CFR 878.4820, Product Code HWE, Class I – Surgical instrument motors and accessories/attachments

Description:

The purpose of this submission is to add a new handpiece and an accompanying software module as a line extension to the current Integrated Power Console IPC® System. The handpiece is powered by the previously cleared Integrated Powered Console. In order to operate the TRITON Electric Handpiece, the IPC will be equipped with the appropriate software module to drive the handpiece. The handpiece is used for sawing, drilling, driving and placing screws, wires and pins when used in conjunction with various attachments previously cleared for use during spinal surgery.

The TRITON Electric High Torque Handpiece has the identical attachment connecting interfacing components as the handpiece cleared under K870157. As a result, the TRITON Electric High Torque Handpiece utilizes the same Attachments and Blades as those cleared under K870157.

Indications for Use:

The TRITON Electric High-Torque Handpiece is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures.

Predicate Device Identification:

The Medtronic TRITON Electric High Torque Handpiece and Software Module is substantially equivalent to the following predicate devices:

Table 1: Predicate Devices for the IPC System with TRITON High Torque Handpiece

Device	Manufacturer	510(k) Number	Clearance Date
XPS 4000 System, Midas Rex Legend EHS System, Integrated Power Console (IPC)	Medtronic Xomed, Inc.	K081475	10/17/2008
XPS 4000 System, Midas Rex Legend EHS System, Integrated Power Console (IPC)	Medtronic Xomed, Inc.	K081277	09/05/2008
IPC® POWEREASETM System 510(k) K111520	Medtronic Xomed, Inc.	K111520	10/26/2011

Comparison to Predicate Device:

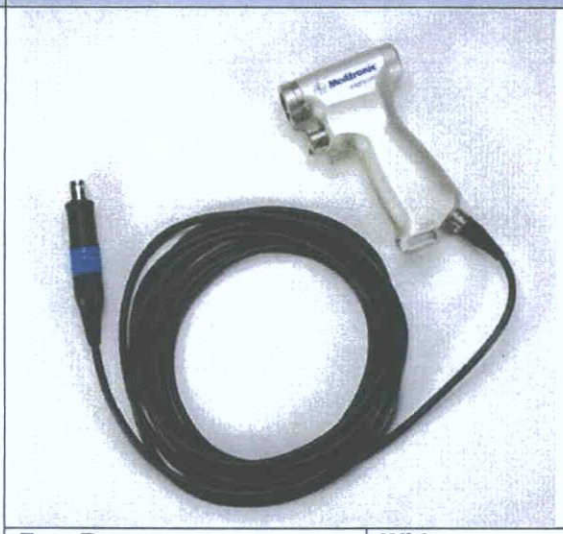
The TRITON Electric High Torque Handpiece and Software Module are similar in device design, function, intended use and fundamental scientific technology to the previously cleared devices listed above.

Table 2: Comparison of Subject Device to Predicate Device

Feature	Proposed IPC™ System w/ TRITON High Torque Handpiece	Predicate Devices
Intended Use	*Integrated Powered Console System w/ TRITON Handpiece* The IPC® system is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial) Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures. The IPC® provides power to various drills and saws to drive	*Integrated Powered Console – K081475* The IPC® system is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial) Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures. The IPC® provides power to various drills and saws to drive attachments and tools during surgical procedures.

Feature	Proposed IPC™ System w/ TRITON High Torque Handpiece	Predicate Devices
	attachments and tools during surgical procedures.	
Indication for Use	*Integrated Powered Console w/ TRITON Handpiece* The IPC® is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial) Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures	*Integrated Powered Console – K081475* The IPC® is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial) Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures
Operating Principle	*Integrated Powered Console w/ TRITON Handpiece* The IPC® System is an electric powered instrument system consisting of multiple handpieces which are powered by the IPC® console. The handpieces are intended to drive various types of interchangeable attachments and instruments used in various surgical procedures. When active, the motor of the handpiece rotates to drive the connected attachment.	*Integrated Powered Console – K081475* The IPC® System is an electric powered instrument system consisting of multiple handpieces which are powered by the IPC® console. The handpieces are intended to drive various types of interchangeable attachments and instruments used in various surgical procedures. When active, the motor of the handpiece rotates to drive the connected attachment.
Software	*Integrated Powered Console w/ TRITON Handpiece* The IPC software is designed to recognize and control position, torque and direction of the following handpieces, POWEREASE Driver, Stylus, Stylus Touch, EHS, Visao, Skeeter and Indigo drills, the Oscillating, Reciprocating and Sagittal saws, and Triton driver and the M4, SC1 microdebriders and the TRITON High Torque Handpiece.	*Integrated Powered Console – K081475* The IPC software is designed to recognize and control position, torque and direction of the following handpieces, Stylus, Stylus Touch, EHS, Visao, Skeeter and Indigo drills, the Oscillating, Reciprocating and Sagittal saws, and Triton driver and the M4 and SC1 microdebriders

Handpiece Comparison

Metric	IPC® with TRITON Electric High Torque Handpiece		Predicate Device
			
	Free Run	**With Attachment**	
Maximum Applied Torque	1.6 Nm	3.1 Nm[1]	7 Nm
Range of Speed	0 to max free run speed of 1250 - 1800 rpm	0 - 250 rpm	0 - 250 rpm
Range of Safe Working Temperatures	Max temperature through the entire operating range at any external surface location on handpiece shall be less than 51 °C for less than 1 minute and shall not exceed 48 °C for less than 10 minutes		48°C max
Duty Cycle	Cycle Time: 20 seconds on maximum / 20 seconds off minimum Maximum number of cycles before resting handpiece: 6 Maximum number of cycles before resting attachment: 3 Minimum rest period: 25 minutes		Continuous Operation
Intended Use	The TRITON Electric High Torque Handpiece is intended to remove hard and soft tissue, drill pilot holes, drive screws, wires, and pins during, but not limited to, spinal, cranial, and small bone surgical procedures. The TRITON Electric High Torque Handpiece is intended to be used in both open and minimally invasive surgical procedures.		The IPC® POWEREASE™ System is indicated for drilling, tapping, and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. It is also used in the placement of screws, or cutting of screws, posts, and rods.

Testing:

Laboratory bench testing conducted on the IPC System with the TRITON Electric High Torque Handpiece demonstrates substantially equivalent performance characteristics to the predicate devices currently on the market.

Conclusion/Summary:

Based upon the laboratory bench test summaries, intended use, and the successful completion of design control activities; the IPC System with the TRITON Electric High Torque Handpiece and software module is shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Surgical Technologies
c/o Mr. Jeffrey Henerson
VP, Quality, Clinical & RA
4620 North Beach Street
Fort Worth, TX 76137

AUG 27 2012

Re: K121264
Trade/Device Name: TRITON Electric High Torque Handpiece and Software Module
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric Cranial Drill Motor
Regulatory Class: Class II
Product Code: HBC, HBE, HRX, HWE
Dated: August 10, 2012
Received: August 13, 2012

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jessica Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121264

4. Indications for Use Statement

510(k) Number (if known): K121264

Device Name: TRITON Electric High Torque Handpiece and Software Module

Indications for Use:

The IPC System with the TRITON Electric High-Torque Handpiece is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K121264